



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No. D440225; **REG. No. /FILE SYMBOL No.:** 91127-O; **ACTION CODE:** R334;
PRODUCT NAME: Propargite Technical; **DECISION No.:** 525427; **PC Code(s):** 097601

DATE: November 20, 2017

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CITAB / RD (7505P)

THROUGH: Shyam B. Mathur, Ph.D.
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11-30-17

TO: Carmen Rodia, Reviewer / Richard Gebken, Product Manager, RM 10
IVB2 / RD (7505P)

SUBJECT: Product Chemistry Review of Propargite Technical

Company Name: Extremis LLC

*Active Ingredient(s): Propargite (91.5%),
MRID No(s): 501225-01 through -04*

*Product ingredient source information may
be entitled to confidential treatment*

INTRODUCTION:

The registrant is seeking to add a new Propargite Technical product to be manufactured site by [REDACTED]. The manufacturing site is supported by the Basic CSF dated December 8, 2016 and product chemistry data supporting Group A&B data in MRID 501225-01 through -04. The Propargite Technical has a label claim for the active ingredient Propargite at a nominal concentration of 91.5% a.i. The registrant claimed that this product is substantially similar to product EPA Reg. No. 400-95 that has a label claim of 90.6% Propargite.

SUMMARY OF FINDINGS:

1. The product chemistry data submitted for Group A corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR §158.320, 158.325, 158.330, 158.340, and 158.350
2. The active ingredient from the five batch analysis ranged from 91.04% to 91.82% for an average of 91.34%. The registrant chose to list 91.5% nominal concentration on both the CSF and the label.
3. The certified limits of the proposed active ingredient and the associated impurities are within EPA's standard certified limits which comply with 40 CFR § 158.175 (b) (2).
4. Product chemistry Group A and Group B data are satisfied.

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5. The registrant stated that there are no impurities of toxicological significance in the Propargite Technical. The impurity profile of this product is not similar to that of the cited product but all the major impurities (above 0.1%) have been characterized.

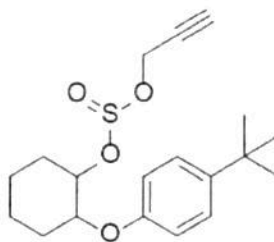
SUMMARY OF FINDINGS:

Table 1. Manufacturing and Impurity Data				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	501225-01	A	
830.1600	Description of materials used to produce the product	501225-01	A	
830.1620	Description of production process	501225-01	A	
830.1670	Discussion of formation of impurities	501225-01	A	
830.1700	Preliminary analysis	501225-01 &-02	A	The NC of AI (91.5%) is supported by an analysis of 5 batches.
830.1750	Certified limits	501225-01 &-02	A	
830.1800	Enforcement analytical method	501225-01 &-02	A	Validated HPLC method
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)				

OPPTS GUIDELINE NO. 830.1550: PRODUCT IDENTITY AND COMPOSITION

Propargite Technical contains 91.5% propargite. The Chemical Code for propargite is 97601 and the CAS No. is 2312-35-8. The CAS nomenclature is 2-[4-(1,1-dimethylethyl)phenoxy]cyclohexyl 2-propynyl sulfite. The IUPAC name is 2-(4-tert-butylphenoxy)cyclohexyl prop-2-ynyl sulfite.

The molecular formula for propargite is $C_{19}H_{26}O_4S$ and it has a molecular weight of 350.5. Its structural formula is shown below:



Propargite

Propargite is a non-systemic acaricide that inhibits mitochondrial ATPase resulting in interruption of normal mite metabolism and respiration. Propargite controls phytophagous mites in a variety of crops and ornamental plants.

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Table 14 Results of Propargite content in Propargite TGA1

Batch No.	20160420	20160421	20160423	20160425	20160437
Propargite (w/w %)	91.74	91.31	91.82	91.04	91.60

830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties

GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	501225-03	A	Pale brown
830.6303	Physical state	501225-03	A	Viscous liquid
830.6304	Odor	501225-03	A	Pungent odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	501225-03	A	Stable at 54 C for 14 days
830.6314	Oxidation/reduction: chemical incompatibility	501225-03	A	No rise in temperature with strong oxidizing agents such as KMnO4 and with reducing agents since no reaction took place to any significant extent
830.6315	Flammability	501225-04	A	Product is not flammable. 71.4 C
830.6316	Explosibility		W	Product does not contain explosive components
830.6317	Storage stability	501225-03	A	Was stable over a period of two weeks at 54 C
830.6319	Miscibility		W.	Product is not an EC nor mixed with petroleum solvents
830.6320	Corrosion characteristics	501225-03	A	Was stable over a period of two weeks at 54 C in a steel drum lined with polyvinyl fluoride
830.7000	pH	501225-03	A	7.36
830.7050	UV/Visible absorption	501225-03	A	See the table below/next page
830.7100	Viscosity	501225-03	A	
830.7200	Melting point		W	Liquid
830.7220	Boiling point	501225-03	A	236.2 °C
830.7300	Density	501225-03	A	1.179 gm/ml @ 20 °C
830.7370	Dissociation constants in water	501225-04	A	pKa above 12
830.7550	Partition coefficient	501225-04	A	Log o/w=5.7
830.7840	Water solubility:	501225-04	A	200 g/L at pH 7 at 20 C

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Table 2: Physical and Chemical Properties

GLN	Requirement	MRID	Status	Result or Deficiency

Test	Test Conditions	Result
UV/Visible Absorption	pH = 7.02	45255 (L/mol·cm) at 196.50 nm
	pH = 1.96	38686 (L/mol·cm) at 197.31 nm
	pH = 10.86	44526 (L/mol·cm) at 198.25 nm
Viscosity	20.0 ± 0.2 °C	1.572 Pa·S
	45.0 ± 0.5 °C	0.132 Pa·S

CONCLUSIONS:

1. Impurities in this product were declared by the registrant to be of little toxicological significance.
2. The product chemistry data requirements have been satisfied.
3. This product is substantially similar to the cited product EPA Reg. No. 400-95 in the percentage of the active ingredient (91.5% vs 90.6%). The cited product has more impurities listed on the CSF dated June 10, 2003.
4. The basic CSF dated December 8, 2016 for the manufacturing site by by Quingdao Hansen Biological Science Company in China is acceptable.

CONFIDENTIAL APPENDIX:

Manufacturing process information may be entitled to confidential treatment

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